

Docket No. RADNT-035C

REMARKS/ARGUMENTS

The foregoing amendment and the remarks which follow are responsive to the final office action dated February 13, 2006.

By the foregoing amendment, the limitations of previously allowed claim 60 have been removed from independent claims 49 and 73 and placed in new dependent claims 79 and 80, in view of the Examiner's revocation of the previously stated allowability of these claims. Additionally, amendments have been made to independent claims 49 and 73 to clarify the claimed subject matter and a minor amendment has been made to claim 54 to correct a typographical error. No new matter has been added.

Claim Objection

By the foregoing amendment, claim 54 has been amended to change the word "hold" to the word "holds" thereby overcoming the objection stated in the office action.

Rejections Under 35 U.S.C. §103

In the office action, all claims were rejected under 35 U.S.C. §103 as being unpatentable over the combination of United States Patent No. 6,749,585 (Aliberto et al.) in view of Wo2001/74263 (Diamantopoulous et al.) alone, or over such combination further in view of either WO 2001/704265 (Mooney et al.), United States Patent No. 6,117,065 (Hastings et al.) or WO 1994/01177 (Hascoet et al.).

As presently amended, independent claims 49 and 73 require the temperature sensor to be 1) affixed to the catheter and 2) moveable from a non-deployed position to a deployed position wherein it does not remain in substantial contact with the blood vessel wall and wherein it is thereby operative to sense the temperature of blood flowing through the subject's vasculature. This combination is not taught or suggested by any prior art of record.

The primary reference, Aliberto et al., does describe an embodiment of a heat exchange

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catheter that has a temperature sensor (100) that is affixed to the catheter, but such affixed temperature sensor (100) is not moveable between a deployed position and a non-deployed position as required in independent claims 49 and 73. Nor does Aliberto et al. suggest any reason or provide any motivation to modify such affixed temperature sensor (100) such that it could move between a non-deployed position and a deployed position as claimed.

The secondary reference, Diamantopoulos et al., does not describe or disclose any heat exchange catheter or any method for controlling body temperature. Diamantopoulos et al. does describe a mapping catheter that has temperature probes that may be deployed outwardly from the such that they remain in substantial contact with contralateral points on the blood vessel wall for thermographic mapping of the blood vessel wall itself, not for measuring the temperature of the blood flowing through the blood vessel. This is clearly distinguishable from Applicant's claimed invention wherein the catheter-affixed temperature sensor, when deployed, does not remain in substantial contact with the blood vessel wall and is thereby operative to sense the temperature of blood flowing through the subject's vasculature. As explained in Applicant's specification, monitoring of the temperature of the blood vessel wall is not necessarily indicative of body temperature and, thus, could lead to an erroneous temperature measurement for Applicant's purposes (see, for example, page 6, paragraph 3). This is especially true in cases, such as those wherein the Diamantopoulos et al. device is used, where the temperature of regions of the blood vessel wall may be elevated due to a localized pathological process.

The tertiary references cited in the Office Action also fail to disclose or render obvious the combinations recited in independent claims 49 and 73. Indeed, as the Examiner recognizes, neither Hascoet et al. nor Hastings et al. nor Mooney et al. even describe or suggest *any* system or method wherein any intravascular heat exchange catheter is used to control the temperature of all or a portion of the body of a human or animal subject.

For example, Hascoet et al. describes a urethral probe that is inserted into the urethra and used to heat the prostate gland as a treatment for prostate disorders. The urethral probe of Hascoet et

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al. does not have any heat exchanges that could be used to exchange heat with blood flowing through the patient's vasculature in combination with a temperature sensor that is moveable from a non-deployed position to a deployed position.

Mooney et al. describes introducers and other device that are insertable into a patient's vasculature and which have temperature sensors that are moveable from non-deployed positions to deployed positions. The devices of Mooney et al. have lumens that may infuse fluids into the patient's blood, but the devices of Money et al. are devoid of any heat exchanger through which a heat exchange fluid may be passed without causing heat exchange fluid to mix with the patient's blood. As required by Applicant's new claims.

Hastings et al. describes a perfusion balloon catheter having a radioactive perfusion tube affixed therein. Preferably, the balloon is helical, having adjacent helical strand windings closely spaced in contact upon inflation to minimize trapped blood and reduce attenuation. The perfusion tube can be made radioactive by inclusion of a helical, radioactive metal coil in the perfusion tube wall. In use, the catheter can be advanced over a guide wire to a stenosis, inflated to dilate the site, with beta radiation from the coil passing through the device to the vessel walls, relatively unhindered by blood.

Conclusion

All claims 49-52, 54, 56-59 and 62-80 are believed to be in condition for allowance. Reconsideration and issuance of a Notice of Allowance is earnestly solicited.

A two (2) month extension is hereby requested under 37 C.F.R. 1.136. The Director is

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hereby authorized to deduct the small entity fee for this extension, as well as the fee for the accompanying Terminal Disclaimer and any other fees due in connection with this filing, from Deposit Account No. 50-0878.

Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

Date: July 13, 2006

Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, California 92618
voice: 949/450-1750
fax: 949/450-1764

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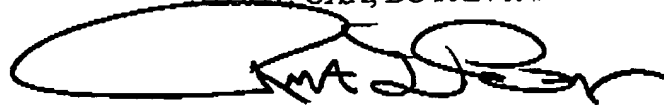
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Respectfully submitted,
STOUT, UXA, BUYAN & MULLINS, LLP

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A handwritten signature in black ink, appearing to read 'R. Buyan', is written over a large, loopy circular flourish.

Robert D. Buyan, Reg. No. 32,460

4 Venture, Suite 300
Irvine, California 92618
voice: 949/450-1750
fax: 949/450-1764